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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,405	04/01/1999	BENGT GUSS	REF/GUSS/P33	1676

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	23

DATE MAILED: 01/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/147,405	Applicant(s) Guss et al.
	Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 20, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above, claim(s) 2-24 and 26-29 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1 and 25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' after-final amendment filed 12/20/2001 (paper no. 21) in response to the final Office Action mailed 10/03/01 (paper no. 20), which amendment has been entered.

Finality Withdrawn

- 2) The finality of the Office Action mailed 10/03/01 (paper no. 20) is hereby withdrawn in view of the new ground of rejection set forth below.

Status of Claims

- 3) Claims 1 and 25 have been amended via the amendment filed 12/20/2001.
Claims 1-29 are pending.
Claims 1 and 25 are under examination.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

- 6) The rejection of claims 1 and 25 made in paragraph 13 of Office Action mailed 10/03/01 (paper no. 20) under 35 § U.S.C. 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendments to the claims.
- 7) The rejection of claims 1 and 25 made in paragraph 14 of Office Action mailed 10/03/01 (paper no. 20) under 35 § U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

Rejection(s) under 35 U.S.C. 112, Second paragraph

- 8) Claims 1 and 25 are rejected under 35 § U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and confusing in the recitation “protein or polypeptide”, because it is unclear what is encompassed in these terms. It is unclear what the differences are, functionally or structurally, between a “protein” and a “polypeptide”.

(b) Claim 25, which depends from claim 1, is also rejected under 35 § U.S.C. 112, second paragraph, as being indefinite, because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

9) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10) Claims 1 and 25 are rejected under 35 § U.S.C. 102(b) as being anticipated by Fiedler *et al.* (EP 350810 A or B), or DE 3583987 A1.

It is noted that the polypeptide or protein, as claimed in claim 1, is structurally undefined. It is recited to have a single function. The breadth of the claims encompasses a purified protein or polypeptide of *Staphylococcus epidermidis* of any molecular weight having any measurable specific or non-specific fibrinogen binding activity.

The limitation “vaccine” in claim 25 is viewed as the intended use of the claimed polypeptide and therefore is not given any patentable weight.

Fiedler *et al.* disclose an isolated and purified polypeptide of *Staphylococcus epidermidis* contained in a pH7 buffer for use in the treatment of infections (see abstract).

The document DE 3583987 A1 discloses an isolated and purified protein of *Staphylococcus epidermidis* (see abstract).

The specific or non-specific fibrinogen binding activity, not explicitly recited by the prior art, is viewed as the inherent property of the prior art polypeptide. Since the Patent Office does

not have the facilities for examining and comparing Applicants' polypeptide or protein with that of the prior art, the burden is on Applicants to show that an obvious difference exists between the claimed invention and those of the prior art. The burden is shifted to Applicants to show that the compound or the product of the prior art does not possess the same structural and functional characteristics of the compound(s) or the product(s) of the instant invention. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Claims 1 and 25 are anticipated by Fiedler *et al.* or DE 3583987 A1.

11) Claims 1 and 25 are rejected under 35 § U.S.C. 102(e) as being anticipated by Katz *et al.* (US 6,107,068), or Alborn *et al.* (US 5,587,307).

It is noted that the polypeptide as claimed in claim 1 is structurally undefined. It is recited to have a single function. The breadth of the claims encompasses a purified protein or polypeptide of *Staphylococcus epidermidis* of any molecular weight having any measurable specific or non-specific fibrinogen binding activity.

The limitation "vaccine" in claim 25 is viewed as the intended use of the claimed polypeptide and therefore is not given any patentable weight.

Katz *et al.* disclose an isolated and purified polypeptide of *Staphylococcus epidermidis* for use in the induction of antibodies (see abstract; Example 13 and column 14, fifth full paragraph).

Alborn *et al.* disclose a recombinant purified protein or polypeptide of *Staphylococcus epidermidis* (see abstract; column 14, first full paragraph; and Example 3).

The specific or non-specific fibrinogen binding activity, not explicitly recited by the prior art, is viewed as the inherent property of the prior art polypeptide. Since the Patent Office does not have the facilities for examining and comparing Applicants' polypeptide or protein with that of the prior art, the burden is on Applicants to show that an obvious difference exists between the claimed invention and those of the prior art. The burden is shifted to Applicants to show that the compound or the product of the prior art does not possess the same structural and functional characteristics of the compound(s) or the product(s) of the instant invention. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Serial Number 09/147,405

Art Unit: 1645

Claims 1 and 25 are anticipated by Katz *et al.*

Remarks

- 12) Claims 1 and 25 stand rejected.
- 13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.
- 14) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

S. DEVI, PH.D.
PRIMARY EXAMINER

January 2002